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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,063	10/01/2003	Jennifer X. Qiao	PH 7500 NP	8093
23914	7590	10/26/2006	EXAMINER	
LOUIS J. WILLE BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			BALLS, ROBERT J	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 10/26/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/677,063

Applicant(s)

QIAO ET AL.

Examiner

R. James Balls

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-22 are pending.
2. This application claims benefit of 60/415,366 filed on October 2, 2002 and claims benefit of 60/417,208 filed on October 9, 2002.
3. Claims 1-10 and 15-22 as they read on the structure of the elected species (structure D) are currently under examination. Claims 1-10 and 15-22, which do not read on the elected species (structure D) as well as Claims 11-14 are withdrawn as being drawn to non-elected subject matter.

### ***Election/Restrictions***

4. The requirement for restriction and election of species was made final in the July 20, 2006 Office action. Nonetheless, applicants contend that the requirement is improper and assert that an additional search is required. Election of species may be required in applications containing both species claims and generic or Markush claims. See MPEP 808.01(a). Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. See MPEP 803.02. In applications where only generic claims are presented, restriction may be required when the generic claims recite such a multiplicity of species that an unduly

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extensive and burdensome search would be necessary to search the entire scope of the claim. See MPEP § 803.02. For further explanation regarding election of species practice, see McGaw, *What is Means When an Examiner Says "Election of Species Requirement,"* Smith & Hopen Article ID: 37 (2005), available online at: [http://www.smithhopen.com/faq\\_display.asp?faq\\_id=37](http://www.smithhopen.com/faq_display.asp?faq_id=37).

In the instant case, a search was conducted in accordance with MPEP 803.02, which delineates the process of search for an election of species. Since the elected species and the core group encompassing the elected species are free of the art, the examiner extended the search to other species of the generic claim. Art was found and cited in the November 28, 2005 office action so the search was terminated and the generic claim rejected. In response, applicants amended the generic claims to overcome the art. Therefore, the examiner revisited the scope of the generic claim and conducted a cursory search of group C (as delineated in applicants' August 8, 2006 remarks, page 79 of 84). The following anticipatory art under 35 U.S.C. §102(b) was found:

El-Naggar et al., Synthesis & Biological Activity of some New 4-(aminoacyl)aminopyridines and 2-(aminoacyl)aminopyrimidine Derivatives, Polish Journal of chemistry, 56(10-12):1279-85 (1982). The chemical structure is shown in El-Naggar et al., STN Accession No. 1984:407623, Registry No. 90303-29-0 (attached hereto).

Since further art was found rendering the generic claim unpatentable the scope is limited to the originally elected species and claims that read on the elected species. See MPEP 803.02.

Should applicants contend that cores A-E are not patentably distinct, applicants should submit evidence or identify such evidence now of record, i.e. show that the compounds of different cores A-E are obvious variants of one another or clearly admit such on the record. Accordingly, if the examiner finds one of the cores unpatentable over the prior art, the evidence or admission that the groups are not patentably distinct will be used in a rejection under 35 U.S.C. §103(a) against the other cores. In the instant case, withdrawal of the restriction requirement would result in an obviousness rejection being applied against all the core structures (A-E) over El-Naggar et al.

Applicants' representative contends that the examiner's search was improper for exceeding the scope of the claimed subject matter. Please refer to MPEP 904.01(b)-(c), where it explains the examiner is required to search the claimed subject matter AND equivalents and analogous art thereof, i.e. subject matter falling outside of the claims but considered relevant by the examiner. Applicants' representative is also attempting to mislead this office by misconstruing the series of events surrounding prosecution of this case. In the August 25, 2006 Remarks, applicants' representative alleged that this office searched the entire scope of the generic claims and indicated them being allowable. Such allegation is misleading since the record clearly indicates on pages 2-3 of the November 25, 2005 Office Action that the examiner searched a number of species and indicated Claim 8 was the only allowable claim. No generic claim has ever been allowed.

***Claim Objections***

5. This application contains claims 1-10 and 15-22 drawn to nonelected subject matter. The requirement for an election of species was made final in the office action mailed on July 20, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Allowable Subject Matter***

6. Claim 8 remains allowable as indicated in the November 25, 2005 Office Action.

***Rejoinder***

7. Applicants requested rejoinder of Claims 11-14 in their response filed on August 25, 2006. However, as explained in the Office Action dated July 20, 2006, methods claims will be rejoined as long as:

- i. The method claims encompass the identical scope as the allowable product; and
- ii. The method claims are free of 35 USC §112 issues.

Currently, there are no method claims drawn to the allowable Claim 8.

Also, the claims are not free of 35 USC §112 issues. They are drawn to treating myocardial infarction, etc. The assay on page 77 supports a method of preventing thrombus formation. Compounds having anticoagulation activity can prevent thrombus formation or continuous thrombosis but cannot necessarily treat the result of such thrombosis, especially when the result is irreversible. One example of the claimed

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scope is treating myocardial infarction. The Cecil Textbook of Medicine explains, "Myocardial infarction is the term used to describe irreversible cellular injury and necrosis occurring as a consequence of prolonged ischemia." Wyngaarden & Smith, CECIL TEXTBOOK OF MEDICINE 247 (Sixteenth Edition). An anticoagulant can relieve future thrombotic events leading to myocardial infarctions but cannot reverse the myocardial infarction or revive the necrotic cardiac tissue, (i.e. cannot treat myocardial infarction.) Currently there is no known way to reverse a myocardial infarction or revive necrotic cardiac tissue. Intervention after a myocardial infarction is to prevent subsequent thrombotic events by maintaining sufficient undamaged tissue for the patients' survival. NOTE: this discussion of treating myocardial infarction is not evidence of a comprehensive search and examination of the non-elected method claims. It is provided merely as one example of a 35 USC §112 issue which precludes rejoinder.

### ***Conclusion***

8. Claim 8 is allowable.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom McKenzie can be reached on (571) 272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R. James Balls  
October 17, 2006



Celia Chang  
Primary Examiner  
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